



Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

**Complete if Known**

Application Number	10/811,793
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<b>Filing Date</b>	<b>March 29, 2004</b>
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First Named Inventor	Plachetka
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Art Unit	1616
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Examiner Name	Choi, Frank I
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Attorney Docket Number

Sheet	2	of	2
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**NON PATENT LITERATURE DOCUMENTS**

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**Examiner  
Signature**

Date  
Considered

8/4/2005

**Signature** M. A. Lee **Considered** ☒ **Not Considered** ☐

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<p>LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)</p> <p><b>1616</b> AUG 05 2004 PATENT &amp; TRADEMARK OFFICE</p>	Atty. Docket No.: 7569/80993	Appl No.: 10/811,793
	Applicant(s) Plachetka, et al.	
	Filing Date: March 29, 2004	Group: <del>to be assigned</del> <b>1616</b>

### U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA 1					
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	AH 1						
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<b>JL</b>	AL 1	Copy of Press Release indicating Non-Approval of MT 100 Product of Pozen. (2004)
	AM 1	
	AN 1	
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	AP 1	
	AQ 1	
	AR 1	
	AS 1	

Examiner <b>JH Choi</b>	Date Considered <b>8/4/2005</b>
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JZ	AI 1	JP 58-8020	Jan. 18, 1983	Japan	A61K	47/00	X	
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JZ	AL 1	Day, <i>et al.</i> , "Evaluation of an Enteric Coated Aspirin Preparation," <i>Aust. N.Z. J. Med.</i> 6:45-50 (1976).
	AM 1	Internet Advertisement for Migraleve. (1998)
	AN 1	Material Safety Data Sheet for Paracetamol D.C. (P.G.S.) (2001)
	AO 1	Abstract for <i>Powder Technology</i> 33:107-111 (1982), Krycer, <i>et al.</i> , "The Role of Intra-Granular Porosity in Powder Compaction."
	AP 1	Abstract for <i>Drug. Dev. Ind. Pharm.</i> 26(8):885-889 (2000), Railkar, <i>et al.</i> , "Evaluation and Comparison of a Moist Granulation Technique to Conventional Methods."
	AQ 1	Abstract for <i>Drug. Dev. Ind. Pharm.</i> 27(4):337-343 (2001), Railkar, <i>et al.</i> , "Use of a Moist Granulation Technique (MGT) to Develop Controlled-Release Dosage Forms of Acetaminophen."
	AR 1	perwent Abstract for JP 58-8020, reference AH above. (1983)
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Examiner: <u>Shih Chen</u>	Date Considered: <u>8/4/2005</u>
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JL	AA I 2,099,402	Nov. 16, 1937	Keller	167	82	Jan. 17, 1934
	AB I 4,024,279	May 17, 1977	Zor, <i>et al.</i>	424	319	Jul. 24, 1975
	AC I 4,235,971	Nov. 25, 1980	Howard, <i>et al.</i>	435	293	Jun. 9, 1978
	AD I 4,380,540	Apr. 19, 1983	Poyser, <i>et al.</i>	424	233	Jan. 18, 1982
	AE I 4,999,226	Mar. 12, 1991	Schock, <i>et al.</i>	424	472	Apr. 27, 1989
	AF I 5,037,823	Aug. 6, 1991	Jones, <i>et al.</i>	514	222.8	Dec. 15, 1989
JL	AG I 5,055,306	Oct. 8, 1991	Barry, <i>et al.</i>	424	482	Oct. 20, 1988

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JL	AH I WO 95/22947	31 August 1995	WIPO	A61P	5/04		
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	AJ I BE 881 967	16 June 1980	Belgium	E07D		X	
JL	AK I CA 2,020,018	27 June 1990	Canada	A61K	31/52		

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JL	AL I	Verwert Abstract for <del>AI above</del> EP 0774253 (1997).
	AM I	<del>Translation for AJI above.</del>
JL	AN I	STN/CAS online, file EMBASE, Acc. No. 1999161935 (Mandell, <i>Cleveland Clinic Journal of Medicine</i> 66:285-292 (1999), Abstract.
JL	AO I	Albibi, <i>et al.</i> , Metoclopramide: Pharmacology and Clinical Application, " <i>Ann. Int. Med.</i> 98:86-95 (1983).
JL	AP I	Andersson, <i>et al.</i> , "Double-Blind Study of Naproxen vs. Placebo in the Treatment of Acute Migraine Attacks," <i>Cephalalgia</i> 9:29-32 (1989).
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	AB 2	5,437,874	Aug. 1, 1995	Bru, <i>et al.</i>	424	466	Jan. 4, 1994
	AC 2	5,573,776	Nov. 12, 1996	Harrison, <i>et al.</i>	424	435	Sep. 8, 1994
	AD 2	5,681,583	Oct. 28, 1997	Conte, <i>et al.</i>	424	472	Apr. 25, 1995
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	AP 2	Chrubasik, <i>et al.</i> , "Paracetamol and Metoclopramide in Fixed Combination," <i>Med. Montasschr. Pharm.</i> 19:110 (1996) (German Language).
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	AM 3	Edmeads, "Four Steps in Managing Migraine," <i>Postgraduate Medicine</i> 85:121-124, 127-128, 131, 132-134 (1989).
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JP	AL 4	Harrington, <i>et al.</i> , "Metoclopramide: An Updated Review of Its Pharmacological Properties and Clinical Use," <i>Drugs</i> 25:451-494 (1983).
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	AM 5	Kumar, "Recent Advances in the Acute Management of Migraine and Cluster Headaches," <i>J. Gen. Intern. Med.</i> 9:339-348 (1994).
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	AO 5	Mathew, "Serotonin 1 <sub>D</sub> (5-HT <sub>1D</sub> ) Agonists and Other Agents in Acute Migraine," <i>Advances in Headache</i> 15:61-81 (1997).
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	AQ 5	Ottervanger, "Ketorolac for Severe Migraine," <i>Med. Sci. Bul.</i> 26:49 (1994).
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SL	AS 5	Peroutka, "Dopamine and Migraine," <i>Neurology</i> 49:650-656 (1997).

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	AN 6	Plosker, <i>et al.</i> , "Sumatriptan: A Reappraisal of Its Pharmacology and Therapeutic Efficacy in the Acute Treatment of Migraine and Cluster Headache," <i>Drugs</i> 47:622-651 (1994).
	AO 6	Pradalier, <i>et al.</i> , "Treatment Review: Non-Steroid Anti-Inflammatory Drugs in the Treatment and Long-Term Prevention of Migraine Attacks," <i>Headache</i> 28:550-557 (1988).
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	AM 7	Schwarzberg, "Application of Metoclopramide Specificity in Migraine Attacks Therapy," <i>Headache</i> 34:439-441 (1994).
	AN 7	Scott, "Dihydroergotamine: A Review of Its Use in the Treatment of Migraine and Other Headaches," <i>Clin. Neuropharmacology</i> 15:289-296 (1992).
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	AQ 7	Tfelt-Hansen, <i>et al.</i> , "The Effectiveness of Combined Oral Lysine Acetylsalicylate and Metoclopramide Compared with Oral Sumatriptan for Migraine," <i>Lancet</i> 346:923-926 (1995).
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	AN 8	Todd, et al., "Naproxen: A Reappraisal of Its Pharmacology, and Therapeutic Use in Rheumatic Diseases and Pain States," <i>Drugs</i> 40:91-137 (1990).
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<u>JS</u>	AS 8	Welch, "Drug Therapy of Migraine," <i>New England J. Med.</i> 329:1476-1483 (1993).

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Date Considered

8/4/2005

LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)	Atty. Docket No.: 7569/80993	Appl No.: 10/811,793
	Applicant(s) Plachetka, <i>et al.</i>	
	Filing Date: March 29, 2004	Group: <sup>1616</sup> to be assigned

### U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	AA						
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	AC						
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### FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	AH							
	AI							
	AJ							
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### OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>JL</i>	AL 9	Wilkinson, <i>et al.</i> , "Migraine and Cluster Headache - Their Management with Sumatriptan: A Critical Review of the Current Clinical Experience," <i>Cephalalgia</i> 15:337-357 (1995).
<i>JL</i>	AM9	Wright, <i>et al.</i> , "Linearity of Metoclopramide Kinetics at Doses of 5-20 mg," <i>Br. J. Clin. Pharmac.</i> 26:469-473 (1988).
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